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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,698	12/02/2002	John Barker	1032-P02047US1	9427

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EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT PAPER NUMBER

3763

DATE MAILED: 04/07/2004

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,698

Applicant(s)

BARKER ET AL.

Examiner

Catherine S. Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-16 is/are allowed.
- 6) ☐ Claim(s) 1-3,6 and 17-21 is/are rejected.
- 7) ☒ Claim(s) 4 and 5 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8.10</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hess et al (US Pat# 5,346,480). Hess discloses a syringe with a retractable needle that has a barrel, a plunger and a needle assembly including a housing (shield/sleeve #23), a needle, a biasing element, and a needle retainer (30). Upon forward displacement of the syringe relative to the needle retainer, the needle is released for retraction by the biasing element. See 2:50-4:31. Regarding methods of providing the structures of the device, performing a medical procedure and retaining the shield, these steps are considered necessary and inherent for proper functioning of the device as disclosed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hess in view of Stiles et al (US Pat# 5,433,712). Hess meets the claim limitations as described above but fails to include a first connector and a second connector.

However, Stiles discloses a self-sheathing hypodermic syringe that includes a first and second connector for attaching a needle to the syringe. See figure 3.

At the time of the invention, it would have been obvious to incorporate the connectors of Stiles into the invention of Hess. Both devices are analogous in the art and with the instant invention. Therefore, a combination is proper. Additionally, leur lock connectors for needle attachment to syringes are well known in the art. It is common knowledge in the art that a leur lock needle connection is advantageous in order to enable a quick change of the needle if a different gauge is needed for a particular application. Therefore, the motivation for the incorporation has support in common knowledge by one skilled in the art, and the combination would have been done to enhance the usability of the device while in a lab or doctors office.

Claims 17 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess in view of Stiles et al (US Pat# 5,433,712). Hess meets the claim limitations as described above but fails to include a first connector and a second connector.

However, Stiles discloses a self-sheathing hypodermic syringe that includes a first and second connector for attaching a needle to the syringe. See figure 3.

At the time of the invention, it would have been obvious to incorporate the connectors of Stiles into the invention of Hess. Both devices are analogous in the art and with the instant invention. Therefore, a combination is proper. Additionally, leur lock connectors for needle

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attachment to syringes are well known in the art. It is common knowledge in the art that a leur lock needle connection is advantageous in order to enable a quick change of the needle if a different gauge is needed for a particular application. Therefore, the motivation for the incorporation has support in common knowledge by one skilled in the art, and the combination would have been done to enhance the usability of the device while in a lab or doctors office.

Hess is view of Stiles meets the claim limitations as described above but fails to teach the method steps of providing a sterile needle assembly, medical apparatus and sealing them in containers

At the time of the invention, it would have been obvious to perform all of the method steps that recite providing sterile structures and containers. Sterilizing syringe components and containing the syringe components pre-assembled or individually is well known in the art. In general, the overall motivation for sterilization and sterilized containment is to prevent infection during use. It is common knowledge in the art that a pre-assembled syringe assembly provides the ability to rapidly perform a procedure. Likewise, it is common knowledge in the art that sterilizing and individually containing a leur lock needle separate from a syringe is advantageous in order to enable a sterile quick change of a needle if a different gauge is needed for a particular application. Therefore, the motivation for sterilization and sterilized containment has support in common knowledge by one skilled in the art, and one motivation, among many in the art, is for enhanced safety to the patient.

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Allowable Subject Matter

Claims 7-16 are allowed. This indication of allowability is based on the assumption that applicant is invoking 112, 6th paragraph means plus function language in claim 7.


Claims 4-5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams 
April 2, 2004


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700